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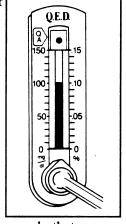
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LABORATORY TESTING OF A SALIVA-ALCOHOL TEST DEVICE BY ENZYMATICS, INC.

New technological advances are introduced in the marketplace from time to time to measure alcohol concentration in the body. One such device is a single-use, disposable saliva-alcohol test device called the Q.E.D.(A150) developed by Enzymatics, Inc. of Horsham, Pennsylvania. While this device was initially designed for use in hospital and other emergency medical settings, its possible highway safety applications prompted a limited laboratory evaluation by the National Highway Traffic Safety Administration (NHTSA).

The manufacturer's instructions for collecting a saliva sample tell the user to put the provided cotton swab around the cheeks, gums and under the tongue for 30-60 seconds. The saturated swab is then placed into the entry port of the test device. This report did not assess the adequacy of the saliva collection procedures, but only evaluated the saliva-alcohol measuring technology. The QED A150 furnishes an alcohol concen-



tration reading within 2 minutes on a scale that resembles an ordinary thermometer. Performance of the device was examined in our laboratory at nine blood alcohol concentrations (BAC) and three temperatures, using repeated trials of spiked samples. The BAC levels were: .02%, .03%, .05%, .06%, .07%, .09%, .10%, .12% and .14% BAC. The three temperatures were room temperature (69.8°F. = 21°C.), a high temperature (95° F. = 35° C.), and a low temperature (50° F. = 10° C.).

Results indicated that the mean BAC levels were about 0.007% BAC units below the known target values. The average standard deviation is about

0.003% For purposes of comparison, performance of evidential breath testers must fall within 0.005% BAC units with a standard deviation not greater than 0.004% to be included on the NHTSA Conforming Products List. In other words, the performance fell just outside of the tolerance required for placement of evidential breath test instruments on the NHTSA Conforming Products List. Performance at low and high temperatures were very similar with a slightly better performance at the low temperature and a slightly worse performance at the high temperature.

It appears that the Q.E.D.(A150) saliva-alcohol test device would be useful for estimating blood alcohol concentrations for screening purposes. Furthermore, the results indicated that the device's performance on these tests consistently underestimated the target BACs at all alcohol concentrations and all three temperatures. From a police enforcement perspective, these under-estimates minimize the likelihood of false-positive readings. These results suggest that it is less likely that police would identify someone as having a BAC above a given threshold when the person being testing is, in fact, not above that level.

A more detailed technical report titled Laboratory Testing of a Saliva-Alcohol Test Device by Enzymatics, Inc. is now available. It may be useful to the police enforcement community as well as other parties interested in new technology developments in the alcohol testing area. However, it should be remembered that this limited laboratory evaluation does not address any issues related to collection of saliva samples or police field use of the device, such as how much saliva is sufficient for a test, possible health and safety concerns for a suspect or an officer, liability concerns for an



agency using the device, and police training requirements. Such issues must be considered prior to reaching a conclusion regarding the practical utility and application of the device.

For additional information about this project, contact: Office of Program Development and Evaluation, Traffic Safety Programs, National Highway Traffic Safety Administration, NTS-32, 400 Seventh Street, S.W., Washington, DC 20590.

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